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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,114	02/21/2002	Kanwarpal S. Dhugga	1301	1712

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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT PAPER NUMBER

1638

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/080,114	DHUGGA ET AL	
	<b>Examiner</b>	<b>Art Unit</b>	
	Medina A Ibrahim	1638	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 13-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 May 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                | Paper No(s)/Mail Date. _____.   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>06/19/02</u> .  | 6) <input type="checkbox"/> Other: _____.                                   |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group I in the reply filed on 04/13/04 is acknowledged. The traversal is on the ground(s) that the inventions I and II are related as they define polynucleotides and polypeptides with sucrose synthase activity. Applicant further argues the inventions have been disclosed as capable of use together. Applicant cites MPEP806.04 and 808.01 to support this position. Applicant therefore, request that claim 12 be rejoined with Claims 1-11 and 13-21. This is not found persuasive because the two groups define independent and distinct inventions for the reasons set forth in the last Office action. In addition, while the polynucleotide of Group I encodes the polypeptide of Group II, the two differ in structure, function and effect, and therefore have different search field. Applicant has provided no evidence that shows inventions I and II are obvious over each other ,and are not patentably distinct. Therefore, the restriction requirement between the polynucleotide and the polypeptide of this application is in compliance with the 35 USC121 and MPEP 806 and 808.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-21 are pending.

Claim 12 is withdrawn from consideration as being drawn to a non-elected invention.

Claims 1-11 and 13-21 are considered in this application.

### ***Sequence Listing***

Applicant's CRF and paper sequence listing of 04/30/02 have been entered. However, the sequence on page 71, lines 25-26, of the specification does not comply with sequence rule 1.801-1.809 because the sequence lacks SEQ ID NO: Applicant must submit a new CRF and paper copy of the Sequence Listing, including the sequence on page 71. Applicant must also amend the specification to include the SEQ ID NO: for the sequence. Also, the sequences of Figures 8 and 9 have not been identified by SEQ ID NO: under the "Brief Description of the Drawing" on page 9 of the specification. On page 9 of the specification, Figures 8 and 9 are described, however no figures are labeled as 8 and 9 in the drawings. Appropriate correction is required.

#### ***Specification***

The disclosure is objected to because of the following informalities: for example page 72, line 7, cites a hyperlink directed to an Internet address. The use of hyperlinks is not permitted under USPTO current policy because the content of such links are subject to a change, resulting in the introduction of New Matter into the specification. Appropriate correction is required.

#### ***Claim Objections***

At claims 1 and 11, "a" before " polynucleotide of SEQ ID NO:" and " polypeptide of SEQ ID NO:" should be changed --the--- because it refers to a specific sequence.

At claim 4, "a" before "recombinant" should be replaced with ---the--- because it refers to a previous claim.

At claim 9, "a polynucleotide of claim 1" should be changed to ---the polynucleotide of claim 1--- because it refers to a previous claim.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the **second paragraph** of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-11 and 13-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite for failing to recite the specific hybridization and wash conditions required for the claimed "stringent hybridization" conditions. Dependent claims 2-11 are included in the rejection because they do not obviate the rejection..

Claims 1 and 11 are indefinite in the recitation of "using primers" and "using GAP", respectively, without any active, positive steps delimiting how this use is actually practiced.

Claim 2 is indefinite because "a member of claim 1" lacks proper antecedent basis. Claim 1 is directed to an isolated polynucleotide.

Claim 8 is indefinite in the recitation of "inducing expression" because expression is a naturally biological phenomena, not an act of man. What is intended by this method step?

Claims 13 and 17 are indefinite for lacking correlation between the preamble and the last method step. Dependent claims 14-15 and 19-21 do not obviate the rejection.

Claims 15 and 19 are indefinite in the recitation of "Sus1, Sus3 and Sh1" which are not art-recognized terms. Appropriate correction is required to more clearly define the metes and bounds of the claims.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 and 13-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the isolated polynucleotide of SEQ ID NO: 1 or 11 encoding a polypeptide with sucrose synthase activity, a recombinant expression cassette, host cells, and transgenic plants/seed comprising said polynucleotide and a method said transformed plants, does not reasonably provide enablement for any polynucleotide having at least 80% sequence identity to SEQ ID NO: 1 or 11, a polynucleotide amplified from *Zea mays* nucleic acids using primers that selectively hybridize to loci within SEQ ID NO: 1 or 11, a polynucleotide which selectively hybridizes under specified hybridization conditions to SEQ ID NO: 1 or 11, a complementary polynucleotide thereof, and a polynucleotide having at least 50 contiguous bases thereof, each encoding a polypeptide having sucrose synthase activity and methods that employ said polynucleotides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to an isolated polynucleotide having at least 80% sequence identity to SEQ ID NO: 1 or 11, a polynucleotide amplified from a *Zea mays* nucleic acid library using primers which selectively hybridize to loci within SEQ ID NO: 1 or 11, a polynucleotide which selectively hybridizes under specified hybridization

conditions to SEQ ID NO: 1 or 11, a complementary polynucleotide thereof, and a polynucleotide having at least 50 contiguous bases thereof, each encoding a polypeptide having sucrose synthase activity. The claims are also drawn to a recombinant expression cassette comprising said polynucleotide in sense or antisense orientation with respect to a promoter, and a method of modulating/increasing level of sucrose synthase by expressing a polynucleotide encoding a sucrose synthase, including Sus1, Sh1, and Sus3 from maize in the stalk tissue, or wherein the encoded protein has 80% identity to SEQ ID NO: 2 and 12 and at least one epitope in common. Transgenic seed and plants including specific monocot and dicot plants are also claimed.

Applicant teaches the isolated polynucleotides of SEQ ID NO: 1 and 11 and other sequences from maize; identification and analysis of said sequences for similarity to all public databases (Examples 1-4). Applicant also teaches general transformation methods of monocot, dicot plants and microbial cell (Examples 5-7). In Examples 9 and 10, Applicant teaches multiple alignments of maize sucrose synthase polynucleotides and polypeptides. Results from Sequence search of the disclosed sequences indicate that SEQ ID NO: 1 and 11 are sucrose synthase sequences. However, Applicant does not expression of said polynucleotides in a transgenic plant, nor that Applicant teaches transgenic plants with increased cellulose synthase concentration in plant tissues.

Applicant has not provided guidance for polynucleotides other than SEQ ID NO: 1 and 11 encoding a polypeptide with sucrose synthase activity. No guidance has been provided for any modification to SEQ ID NO: 1 that resulted in the polynucleotides of

claims 1 (parts (a), (c), (d) and (g). Applicant has not provided guidance with respect to regions or 50 contiguous bases of the full-length sequence that are sufficient to encode a functional polypeptide having the desired activity. In the absence of such guidance, undue experimentation would be required to screen through the myriad of different polynucleotides having 80% identity to SEQ ID NO: 1 or 11 thereto, and all possible 50 contiguous bases thereto, to identify those that are capable of encoding a polypeptide having the desired functional activity, and determine which would also affect sucrose synthase levels in stalk tissues through the myriad of transgenic plants transformed with said polynucleotides.

The state of the art for isolation of cDNA or genomic clones with specific function is highly unpredictable. Significant guidance is required with respect to hybridization and wash that will allow specific isolation of the target genes from all natural sources. In the absence of specific guidance, undue trial and error experimentation would be required to screen through the vast number of plant and non-plant cDNA and genomic clones to identify those that encode a functional sucrose synthase, and determine through the myriad of plant transformation which polynucleotides would also affect sucrose synthase concentration in a plant.

Therefore, given the lack of guidance as discussed supra, the unpredictability; lack of working examples, the state of the art, one skilled would not be able to practice the invention as broadly claimed. See, *In re Wands* (858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)). See also *Amgen Inc. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d

1016 at 1027 (Fed. Cir. 1991) where the court held that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof.

***Written Description***

Claims 1-11 and 13-21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a multitude of polynucleotide having at least 80% sequence identity to SEQ ID NO: 1 or 11, all polynucleotides amplifiable from a *Zea mays* nucleic acid library using primers which selectively hybridize to loci within SEQ ID NO: 1 or 11, a polynucleotide which selectively hybridizes under specified hybridization conditions to SEQ ID NO: 1 or 11, a complementary polynucleotide thereof, and a polynucleotide having at least 50 contiguous bases thereof, each encoding a polypeptide having sucrose synthase activity. The claims are also drawn to a recombinant expression cassette comprising said polynucleotide in sense or antisense orientation with respect to a promoter, and a method of modulating/increasing level of sucrose synthase by expressing a polynucleotide encoding a sucrose synthase, including Sus1, Sh1, and Sus3 from maize, in the stalk tissue. Transgenic seed and plants including specific monocot and dicot plants are also claimed. In contrast, the specification only describes SEQ ID NO: 1 or 11 and other polynucleotides also from maize. These are genus claims.

The claimed invention does not meet the current written description requirements for the following reasons. Firstly, Applicant has neither described the functional domains necessary for sucrose synthase activity nor has shown phenotypic effects of SEQ ID NO: 1 or 11 in a transgenic plant/cell. Secondly, substantial variation in structures and function are expected among polynucleotides amplified from Zea mays nucleic acid library using primers which selectively hybridize to loci within SEQ ID NO: 1 or 11, polynucleotides that share any 50 contiguous bases of SEQ ID NO: 1 or 11. Thirdly, Applicant has not described a single variant having the structural and functional properties as recited in the claims. In addition, since Applicants has not described the polynucleotides as discussed above, the recombinant expression cassettes, host cells, and the transgenic plant/plant cell/seeds comprising said polynucleotides are similarly not described. Therefore, given all the reasons above, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that one skilled in the art would recognize that Applicants are in possession of the invention as broadly claimed. Therefore, the written description requirement is not satisfied.

See Written description Examination Guidelines published in Federal Registry/Vol. 66, No.4/Friday, January 5, 2001/Notices). See, also *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997) where it states "A description of a genus of cDNA may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the

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scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 13, 16-17 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Hesse et al (US 5, 866,790).

The claims are drawn to a method of increasing cellulose production or cellulose concentration by transforming a plant cell with a recombinant expression cassette comprising a sucrose synthase polynucleotide operably linked to a seed or stalk specific promoter, regenerating a plant from said plant cell, wherein the polynucleotide is expressed for a time sufficient to modulate/increase the level of sucrose synthase.

Hesse et al teach a method of transforming plant cells from sugar beet with a DNA construct comprising a nucleic acid sequence encoding a sucrose synthase (SEQ ID NO: 5 and 6) operably linked (in sense or antisense orientation) to a promoter that directs expression in seed or stem tissues, and transformed plants expressing said

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polynucleotide regenerated from the transformed plant cells (columns 26-27; Examples 2-4; and claims ). Therefore, Hesse et al teach all claim limitations.

Claims 1-11 and 13-14, 16-18, and 20-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Cheikh et al (US 20030135870, filed 26/01/1999).

The claims are drawn to an isolated polynucleotide amplified from *Zea mays* nucleic acids using primers which selectively hybridize, under stringent hybridization conditions, to loci within the polynucleotide of SEQ ID NO: 11, or a polynucleotide comprising at least 50 contiguous bases of SEQ ID NO:11, a recombinant expression cassette comprising said polynucleotide operably linked to a seed-specific or stalk specific promoter, specific monocot and dicot plants transformed with a said polynucleotide, transgenic seed, and a method of modulating/increasing level of sucrose synthase or cellulose production in a transgenic tissues.

Cheikh et al teach isolated nucleic acid from maize comprising 255 contiguous bases of SEQ ID NO: 11 (see attached Sequence Search Results), and encoding a polypeptide having sucrose synthase activity, DNA constructs, and vectors for plant transformation tissue specific promoters including, pericarp/seed and stalk-specific promoters (pages 32-34; paragraphs 266-276). The cited reference further teaches transformation and regeneration of monocots and dicots, transgenic seeds, antisense and sense expression and methods for modulating level of sucrose/sucrose synthase in specific plant tissues ((pages 35-39). Therefore, Hesse et al teach all claim limitations.

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**Remarks**

The polynucleotide of SEQ ID NO: 1 and 11 and polynucleotides encoding SEQ ID NO:2 or 12 are free of the prior art.

No claim is allowed.

**Contact information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM. Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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6/23/04

Mai

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